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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
d18086

Refer to: CFN 1124458
MQSA ID #189183

Baltimore District Office
900 Madison Avenue
Baltimore, Maryland 21201

May 12, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Cliff R. Livesay, President
Shenandoah Valley Mobile X-Ray, Inc.
110 B East High Street
Woodstock, Virginia 22664

Dear Mr. Livesay:

On March 2, 1998, Investigator Elizabeth A. Laudig of the Food and Drug Administration (FDA), Baltimore District Office, and Regional Radiological Health Representative (RRHR), Heyward L. Rourk, Jr., of the FDA, Central Region, visited your facility. The purpose of their visit was to investigate an anonymous telephone complaint referred to the FDA alleging that Shenandoah Valley Mobile X-Ray, Inc. (Shenandoah) was conducting mammography without a valid FDA Mammography Facility Certificate (FDA certificate). The Mammography Quality Standards Act of 1992 (MQSA) provides that no facility may conduct examinations or procedures involving mammography after October 1, 1994, unless the facility obtains an FDA certificate (42 U.S.C. 263b(b)(1)(A)). In a telephone conversation with RRHR Rourk on March 2, 1998, you stated that you would immediately cease conducting mammography examinations or procedures until Shenandoah applied for and was issued a valid FDA certificate.

Investigator Laudig and RRHR Rourk met with you on March 13, 1998 to further investigate the complaint. A second and final meeting was held with you at your office on March 19, 1998 to complete their investigation.

During their March 13, 1998 visit, Investigator Laudig and RRHR Rourk recovered the following expired FDA certificates from your office and mobile van:

- Six-Month Provisional Mammography Facility Certificate
  # (None) Expiration date: March 31, 1995;

- Six-Month Provisional Certificate (Reinstated facility undergoing accreditation)
  [redacted] Expiration date: December 22, 1995;

- Six-Month Provisional Certificate (Reinstated facility undergoing accreditation) [redacted] Expiration date: February 15, 1997;

- Six-Month Provisional Certificate (Reinstated facility undergoing accreditation) [redacted] Expiration date: April 21, 1997; and

- Six-Month Provisional Certificate (Reinstated facility undergoing accreditation) [redacted] Expiration date: April 21, 1997.

On November 11 and 22, 1996, Provisional Mammography Facility Reinstatement Certificates [redacted] and [redacted], respectively), bearing the expiration date of April 21, 1997, were issued to your facility. However, in a letter dated December 16, 1996, the American College of Radiology (ACR) informed you that effective that day, your facility's mammography accreditation application would be considered inactive because of your facility's failure to comply with the film submission time constraint requirements. ACR advised you that it would be notifying the FDA of the inactivation.

In a letter dated December 18, 1996, FDA informed you that ACR had denied your facility's accreditation because your facility failed to meet the requirements for accreditation. Under MQSA, FDA could not provide certification to a facility that was not accredited. The letter had a Fact Sheet enclosed which outlined the steps that you were to take because your facility had been denied accreditation and was no longer certified by FDA.

Our recent investigation revealed that Shenandoah conducted mammography examinations or procedures at public and private sector work sites in the Commonwealth of Virginia, State of Maryland, and District of Columbia without ACR accreditation and a valid FDA certificate on multiple occasions including, but not limited to:

1996: February 19 and 20; March 11; April 20 and 23; May 20 and 21; June 6, 19, 20 and 21; September 10, 11 and 12

1997: June 24 and 25; September 29 and 30; October 1

1998: February 16, 17 and 18

Our investigation also revealed that your facility failed to comply with the minimum standards for documentation required for legal operation of a mammography facility. The following failures to comply with the minimum quality standards for mammography were identified:

Personnel Requirements - Interpreting Physician (21 CFR 900.12(a)(1))

There was no documentation available to substantiate that the interpreting physician, [redacted]

[redacted]

1) had met either the requirement of being board certified by any of the approved boards (21 CFR 900.12(a)(1)(ii)(A)); or

had two months full-time training in the interpretation of mammograms (21 CFR 900.12(a)(1)(ii)(B)); and

had met the initial training requirement of having received 40 hours of continuing medical education in mammography (21 CFR 900.12(a)(1)(ii)(C)); and

2) had met the initial experience requirement of having read and interpreted mammograms from the examinations of at least 240 patients in the six months preceding the application (21 CFR 900.12(a)(1)(iii)(A)); or

had read and interpreted mammograms of at least 240 patients in the six months preceding the application under the direct supervision of a qualified interpreting physician (21 CFR 900.12(a)(1)(iii)(B)); and

3) had met the continuing experience requirement of having read and interpreted mammograms from an average of 960 patient examinations per month over 24 months (21 CFR 900.12(a)(1)(iv)(A)); and

had met the continuing experience requirement of having completed a minimum of 15 credits in mammography over the previous 36-month period (an average of five credits/year) (21 CFR 900.12(a)(1)(iv)(B)).

Personnel Requirements - Radiologic Technologist (21 CFR 900.12(a)(2))

There was no documentation available to substantiate that Radiologic Technologist [redacted] or any other radiologic technologist ever employed by the facility who performed mammography after October 1, 1994:

1) had met the requirement of either being licensed by a State (21 CFR 900.12(a)(2)(i)) or board certified by any of the bodies approved by FDA to certify radiologic technologists (21 CFR 900.12(a)(2)(ii)); and

2) for those radiologic technologists associated with facilities that applied for accreditation before October 1, 1996, had met the requirement of having received specific training in mammography, either through a training curriculum or special mammography course, and had accumulated at least an average of five continuing education units per year related to mammography (21 CFR 900.12(a)(2)(iii)(A)); and

3) had one year of experience in mammography and by October 1, 1996, had met the requirement of having received specific training in mammography, either through a training curriculum or special mammography course, and had accumulated at least an average of five continuing education units per year related to mammography (21 CFR 900.12(a)(2)(iii)(B)).

Quality Assurance - Equipment (21 CFR 900.12(d)(1))

There was no documentation available to substantiate that:

1) processor Quality Control (QC) tests were performed since January 1996 (21 CFR 900.12(d)(1)(i));

2) QC tests were performed and charted or recorded for the following: Darkroom Fog; Screen Film Contact; Fixer Retention Analysis; and Compression (21 CFR 900.12(d)(1)(i)); and

3) a Quality Assurance (QA) program was in place. Missing items included the following: Personnel Responsibilities; QC Test Procedures; Equipment Use and Maintenance; Procedures; Technique Tables/Charts; and Service Records (21 CFR 900.12(d)(1)(i)).

Quality Assurance - Phantom Images (21 CFR 900.12(d)(2))

1) There were no phantom image QC charts present (21 CFR 900.12(d)(2)).

2) The phantom images taken between April 1996 through January 1998 received failing scores (21 CFR 900.12(d)(2)).

Quality Assurance - Clinical Images (21 CFR 900.12(d)(3))

There was no documentation available to substantiate that repeat analysis was performed (21 CFR 900.12(d)(3)(i)).

Quality Assurance - Clinical Image Interpretation (21 CFR 900.12(d)(4))

There was no documentation available to substantiate that a medical audit system to track positive mammograms was in place (21 CFR 900.12(d)(4)).

Quality Assurance - Surveys (21 CFR 900.12(d)(5))

There was no documentation available to substantiate that:

1) a medical physicist survey had been performed for the X-Ray system since August 1996 (21 CFR 900.12(d)(5)); and

2) corrective actions were taken when called for in the medical physicist's survey report (21 CFR 900.12(d)(5)).

Quality Assurance - Medical Records (21 CFR 900.12(e))

There was no documentation available to substantiate that a lay summary of the mammography report was provided to self-referred women (21 CFR 900.12(e)(2)(ii)(B)).

Finally, an application was not submitted to an accreditation body and a valid FDA certificate was not obtained since the facility was denied accreditation on December 18, 1996 (21 CFR 900.11(a)).

As a result of our investigational findings, FDA has serious concerns about the quality of mammography performed by Shenandoah. Therefore, FDA is requesting that Shenandoah Valley Mobile X-Ray, Inc. contact ACR and arrange to have an Additional Mammography Review (AMR) conducted to assess the quality of all mammography performed by Shenandoah.

Shenandoah will be responsible for the payment of all fees charged by ACR for conducting the AMR. The review will assess whether there has been a compromise of quality sufficient to pose a serious risk to human health. If the results of the AMR indicate that the quality of mammography produced by your facility poses a serious risk to human health, FDA may request that your facility submit a plan for a patient notification program.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- Your future plans for conducting mammography; and

- Whether you intend to request an AMR by the ACR and, if the results of the AMR reveal that there has been a compromise of quality sufficient to pose a serious risk to human health, if you intend to conduct a patient notification program.

Please send your written response to:

Mr. Scott J. MacIntire, Compliance Officer
Food and Drug Administration
10710 Midlothian Turnpike, Suite 424
Richmond, Virginia 23235-4766

Additionally, FDA regulations do not preclude States and local jurisdictions from independently enforcing their own laws and regulations. In some cases, those requirements may be more stringent than FDA's. Therefore, when you plan your corrective actions, you should consider the more stringent State or local jurisdictional requirements, if any.

FDA's investigational findings demonstrate that your facility has engaged in serious violations of the MQSA, including performing mammography examinations or procedures without a valid FDA certificate and otherwise failing to comply with the MQSA. FDA may, without further notice, initiate further regulatory action(s) such as:

Assessing civil money penalties in an amount not to exceed $10,000 against an owner, operator, or any employee of a facility required to have a certificate, for:

- **failure** to obtain a certificate (42 U.S.C. 263b(h)(2)(A)),
- **each failure** to substantially comply with the quality standards (42 U.S.C. 263b(h)(2)(B)), and
- **each violation**, or **for aiding or abetting in a violation** of any provision of the MQSA or FDA's implementing mammography regulations (21 CFR Part 900) (42 U.S.C. 263b(h)(2)(C)).

Seeking an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health (42 U.S.C. 263b(j)).

If you have any questions regarding this letter or your response, you may contact Mr. MacIntire at (804) 379-1627, extension 14.

Sincerely yours,

Elaine Knowles Cole
Director, Baltimore District